REMARKS

Claims 1-44 are pending in the application. Claims 1, 3, 17, 22 and 37 are amended.

In the October 29, 2003 Office Action, the Examiner rejected claims 1-3, 7-10, 12-17, 20-23, 25, 37-38 and 40-44 under 35 USC §102(e) as being anticipated by U.S. Patent 6,358,201 to Childre et al. ("Childre"). As set forth below, all the claims are believed to be allowable as presented and therefore, this rejection is respectfully traversed. The noted claims include four independent claims (i.e., claims 1, 17, 22 and 37).

Independent claims 1 and 37 are directed to monitoring a Mayer wave effect isolated from a plethysmographic waveform. As will be appreciated, obtaining physiological parameter information related to the Mayer wave requires distinguishing effects in the pleth waveform cased by the Mayer wave from other effects, e.g., caused by a patient's respiration. This raises certain difficulties in view of the fact that some of these components (e.g., respiration) can occur within overlapping frequency ranges. However, it has been recognized that by transforming a time-based pleth waveform signal into a frequency domain signal (i.e., into spectral information), the effects of the Mayer wave are more readily isolated from other effects for monitoring purposes. In this regard, the spectral composition of the Mayer wave can be readily characterized and conveniently analyzed. Accordingly, each of independent claims 1 and 37 utilizes a frequency based analysis of a time-based pleth waveform signal to better isolate Mayer wave effects.

The method of claim 1 involves obtaining a time-based pleth waveform signal that is modulated based on interaction of transmitted optical signals with a patient's blood. This time-based pleth waveform signal is transformed into a frequency domain in order to obtain spectral information including at least first information associated with a fundamental frequency of the pleth waveform. Once the pleth waveform signal is transformed, the resulting spectral information may be further

processed to identify effects (i.e., physiological parameter information) related to the Mayer wave. For example, once transformed into spectral information, the Mayer wave component of the spectral information signal may be readily identified through frequency-based filtering. Accordingly, an output related to the identified Mayer wave effect is provided.

Independent claim 37 provides an apparatus that is operable to transform a time-based pleth waveform signal into a frequency-based spectral information signal for use in identifying Mayer wave effects. As will be appreciated, the ability to perform this transform enables the apparatus to provide spectral analysis of a pleth waveform signal and thereby more readily separate the effects of respiration from the effects of the Mayer wave in a pleth waveform signal.

Childre does not disclose the structure/methodology discussed above in relation to independent claims 1 and 37. By way of example, Childre fails to transform a time-based pleth waveform signal into a frequency domain in order to obtain spectral information that includes first information associated with a fundamental frequency of the pleth waveform signal. Childre monitors a heart rate variability (HRV) waveform. As defined by Childre, heart rate variability is a measure of the naturally occurring beat-to-beat changes in heart rate. See Childre Column 2 lines 43-46. In this regard, Childre utilizes a time-based pleth signal or ECG signal to identify pulse intervals, which are utilized to generate a HRV waveform that is subsequently analyzed using spectral analysis techniques. See Column 2 lines 59-63. In order to generate a HRV waveform, a heart beat is monitored and the time interval between heart beats is determined for a set of data samples. The variation of the each time interval, as compared to an average time interval for the set of data samples, is plotted to generate the HRV waveform. See Column 11, line 52 – Column 13, line 12. The resulting HRV waveform is then transformed into the frequency domain for spectral analysis. Column 13, lines 44-56. While Childre transforms a signal into a frequency domain for spectral

analysis, the signal is not the pleth waveform signal. Accordingly, Applicant request that this rejection be withdrawn.

Independent claim 17 provides a method for monitoring low frequency blood volume variations within a patient. The method includes obtaining a time-based pleth waveform signal and transforming that signal into a frequency domain in order to obtain a spectral information signal. This spectral information signal will include at least a first peak associated with a fundamental frequency of the pleth waveform signal, which will typically be associated with the heart rate of the patient. Based on this fundamental frequency, the spectral information signal is further processed to obtain information regarding a low frequency blood volume variation of the patient that relates to a second peak of the spectral information signal. This second peak may be located in a frequency band between about 0.05 Hz and 0.5 Hz. Accordingly, this low frequency blood volume variation may be monitored over time to identify a characteristic of interest. In this regard, an amplitude and/or frequency of the low frequency blood volume variation may be monitored.

As noted above, Childre fails to transform a pleth waveform signal into a frequency domain to obtain a spectral information signal. Accordingly, Childre fails to disclose or suggest determining, inter alia, blood volume variability from the spectral information signal or monitoring such a blood volume variation for a characteristic of interest. Accordingly, Applicant request that this rejection be withdrawn.

Independent claim 22 provides a method generating heart rate variability information from a spectral signal for monitoring purposes. In this regard, a time-based pleth waveform signal is obtained for a patient. A Fourier transformation is performed to transform the time-based pleth waveform signal into a spectral information signal in a frequency domain. This spectral information signal is then processed to obtain heart rate information, which may in turn be processed to obtain

information regarding heart rate variability. The heart rate variability information may be monitored to identify a characteristic of interest therein. In one particular embodiment, the step of first processing comprises obtaining a time series of heart rate values from the spectral information signal to provide the time series of heart rate values. In this regard, the method provides for transforming the time-based signal into a frequency-based signal and plotting one or more components of the frequency-based signal back into the time domain. This allows for trending effects that have been isolated from a pleth waveform signal through spectral analysis.

Childre does not disclose or suggest generating heart rate variability information from a spectral signal for monitoring purposes. As noted above, Childre utilizes a time-based pleth signal or ECG signal to identify pulse intervals, which are utilized to generate a HRV waveform that is subsequently analyzed using spectral analysis techniques. In this regard, Childre teaches away from the method claimed in independent claim 22. Accordingly, Applicant request that this rejection be withdrawn.

The Examiner also rejected claims 4-6, 11, 18-19, 24, 26-28 and 39 under 35 USC §103(a) as being unpatentable over Childre in view of U.S. Patent 6,519,486 to Edgar, Jr. et al. ("Edgar"). This rejection is traversed.

Initially, Applicant submits that each above-noted claim depends from an allowable base claim. Furthermore, Applicant submits the proposed combination fails to yield the subject matter of the above-noted claims. Edgar is directed to a method for removing motion artifacts from devices for sensing body parameters. See Abstract. Childre is directed toward performing a spectral analysis of a heart rate variability signal for the purpose of achieving a state of autonomic balance between the sympathetic and parasympathetic branches of the nervous system. See Column 10 lines 12-30. Assuming the combination proposed by the Examiner is proper, neither of the cited references

suggests transforming a pleth waveform signal into a frequency domain for monitoring purposes. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Based upon the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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